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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/922,405	08/03/2001	Charles A. Nicolette	GZ 210300	7264
7590 02/05/2004			EXAMINER	
DEBORAH A. DUGAN, GENZYME CORPORATION 15 PLEASANT STREET CONNECTOR FRAMINGHAM, MA 01701-9322			RAWLINGS, STEPHEN L	
			ART UNIT	PAPER NUMBER
			1642	

DATE MAILED: 02/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/922,405

Applicant(s)

NICOLETTE, CHARLES A.

Examiner

Stephen L. Rawlings, Ph.D.

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-9 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

1. The election with traverse filed October 29, 2003 is acknowledged and has been entered.

2. Claims 1-9 are pending in the application and are currently subject to restriction.

Election/Restrictions

3. Upon further consideration, the previous restriction is vacated and replaced by the following new restriction. Applicant's arguments, to the extent that they still apply, are addressed below.

4. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-3, drawn to compositions comprising immunogenic ligands, classified in class 424, subclass 185.1.

II. Claims 4-8, drawn to host cells comprising immunogenic ligands, classified in class 435, subclass 325.

III. Claim 9, drawn to a method of inducing an immune response, classified in class 424, subclass 185.1.

5. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to two entirely different products, i.e. compositions versus cells which are classified separately and which require non-cohesive searches and considerations. While each group includes the same peptide

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ligands, the searches and considerations for cells versus compositions are non-cohesive.

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the compositions may be used for *in vitro* immunoassays and for antibody screening.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for any single group is not required for any other group, restriction for examination purposes as indicated is proper.

7. This application contains claims directed to the following patentably distinct species of the claimed invention, wherein said immunogenic ligands are selected from the group consisting of:

- a) SEQ ID NO: 3;
- b) SEQ ID NO: 5;
- c) SEQ ID NO: 7;
- d) SEQ ID NO: 9;
- e) SEQ ID NO: 11;
- f) SEQ ID NO: 13;
- g) SEQ ID NO: 15;
- h) SEQ ID NO: 17;
- i) SEQ ID NO: 19;
- j) SEQ ID NO: 21;
- k) SEQ ID NO: 23; and

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I) SEQ ID NO: 25.

Each of groups I-III requires a combination of at least 2 of the above species of peptide. Each species of peptide is a different product, having a different sequence and requiring a unique search that is not required of any of the other species of peptide. The search of any single species of peptide will not provide adequate information regarding any of the other different species of peptide. It is recognized that each group specifies the presence of at least two species of immunogenic ligand in a combination which two species may be selected from a recited Markush group. The examiner notes that the presence of one novel and nonobvious peptide ligand within a specifically claimed combination would render the combination allowable over the prior art (but not necessarily over 35 U.S.C. 101 and 112). The examiner also acknowledges applicant's argument regarding the practice of searching 10 nucleotide sequences set forth in MPEP 803.04. However, this policy was limited to simple nucleic acid sequences and did not encompass amino acid sequences. Further, the office no longer has the resources to permit simultaneous search of unrelated sequences.

Applicant is required under 35 U.S.C. 121 to specifically elect at least two species of peptide ligand from the Markush group, which two specific disclosed species will be considered for prosecution on the merits and to which the claimed combinations shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

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Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

8. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Conclusion

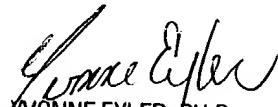
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (571) 272-0836. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne L. Eyler, Ph.D. can be reached on (571) 272-0871. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Stephen L. Rawlings, Ph.D.
Examiner
Art Unit 1642

slr
January 26, 2004


YVONNE EYLER, PH.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600